THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL J. MARIANT and GENE SAMSON

Appeal No. 1999-2029 Application No. $08/431,360^{1}$

ON BRIEF

Before McQUADE, NASE, and CRAWFORD, <u>Administrative Patent</u>
<u>Judges</u>.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 20, which are all of the claims pending in this application.

We AFFIRM-IN-PART.

¹ Application for patent filed April 28, 1995.

BACKGROUND

The appellants' invention relates to an occlusive device, and typically includes a substrate, often a helical metal coil, and a multiplicity of fibers incorporated therewith for enhancing a tissue-ingrowth response for occlusion (specification, p. 1, lines 17-20). An understanding of the invention can be derived from a reading of exemplary claims 1 and 7, which appear in the appendix to the appellants' brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Phelps et al. 5,382,259 Jan. 17, 1995 (Phelps)
Dormandy, Jr. et al. 5,382,260 Jan. 17, 1995 (Dormandy)

Claims 1 through 11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Phelps.

Claims 12 through 20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Dormandy in view of Phelps.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the answer (Paper No. 11, mailed October 24, 1997) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 10, filed October 6, 1997) and reply brief (Paper No. 12, filed December 29, 1997) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a case of obviousness.

See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956

(Fed. Cir. 1993). A case of obviousness is established by presenting evidence that the reference teachings would appear

to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed combination or other modification. See In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Furthermore, the conclusion that the claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Rejections based on § 103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. The examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. See In <u>re Warner</u>, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), <u>cert. denied</u>, 389 U.S. 1057 (1968).

With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

Phelps discloses a vasoocclusion coil comprising: (a) a helical coil which may be segmented, continuous, or segmented having a gap between the two end portions, but in each case having a first end and a second end; and (b) at least one fibrous woven or braided tubular element or covering attached to the exterior of the helical coil. Phelps teaches (col. 2, lines 39-44) that the coil will typically be made of a radiopaque material such as platinum, tungsten, gold, silver, or alloys thereof, or other suitable generally radiopaque metals which are otherwise biologically inert. Phelps also teaches (col. 2, lines 54-66) that

[t]he fibrous woven or braided tubular member (130) may be made from a biocompatible materials such as Dacron[®] (polyester), polyglycolic acid, polylactic acid, fluoropolymers (polytetrafluoroethylene), nylon (polyamide), or silk. The strands forming the braid should be reasonably heavy, e.g., having tensile strength of greater than about 0.15 pounds. The materials mentioned, to the extent that they are thermoplastics, may be melted or fused to the coils. Alternatively, they may be glued or otherwise fastened to the coils. Preferred materials are Dacron[®] strands using the process of fusing to attach the strands to the coil surface.

In Figure 6, the tubular member has tassels 148 which extend past the end of the coil. Phelps states that this feature provides additional occlusion area and adds very little to the volume of the device as it passes through the catheter lumen. In Figure 11, the fibrous braided portion 166 is constructed to have exposed fiber elements 168 sticking out from the fiber braided portion 166 to enhance the ability of the device to effectively fill the space at the target within the patient's vasculature.

Dormandy discloses an embolization device comprising an elongate coil having a plurality of turns and a group of fibers. The group of fibers has an intermediate portion and first and second end portions. The intermediate portion is looped about one of the turns of the coil to form a loop on one of said turns. The end portions extend interiorly of the coil and outwardly of the coil through two adjacent turns adjacent the turn about

which the loop is formed. The ends of the fibers of the end portions of each group are free to move. The group of fibers is free of knots and the loop serves as the sole means for retaining the group of fibers on the coil. Dormandy teaches (column 2, lines 58-61) that the coil is formed of a metal which is relatively opaque to x-rays and may be made of a material such as stainless steel, copper, gold, or platinum alloys. Dormandy also teaches (column 3, lines 27-28) that the fiber is formed of a suitable synthetic medical grade material such as Dacron®.

Claims 1 through 6

We will not sustain the rejection of claims 1 through 6 under 35 U.S.C. § 103.

Claim 1 reads as follows:

A method for making a device for occluding a lumen or cavity in a mammal, comprising the steps of:

- (a) bringing fibers into contact with a substrate to form an interface therebetween; and
- (b) causing the substrate to emit heat so the fibers at the interface are secured to the substrate.

The examiner's position with respect to claim 1 is that whatever the source of heat is which fuses the Phelps et al. strands to the coils would obviously heat the coils

themselves since the coils are located adjacent to the strands and are, in fact touching the strands. Since the coils are obviously heated they would, in turn, emit heat to the fibers.

The appellants argue that there is no teaching or suggestion within Phelps to arrive at the invention as set forth in claim 1. Specifically, the appellants believe that (1) Phelps suggests only applying a heat source around (i.e., external to) a fibrous member-encased coil, and (2) Phelps does not suggest applying a heat source internal to the fibrous member-encased coil.

Evidence of a suggestion, teaching, or motivation to modify a reference may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), Para-Ordinance Mfg. v. SGS Imports Intern., Inc., 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the

pertinent references," In re Rouffet, 149 F.3d 1350, 1355, 47
USPQ2d 1453, 1456 (Fed. Cir. 1998). The range of sources
available, however, does not diminish the requirement for
actual evidence. That is, the showing must be clear and
particular. See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc., 157
F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). A
broad conclusory statement regarding the obviousness of
modifying a reference, standing alone, is not "evidence."
E.g., McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576,
1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993); In re Sichert,
566 F.2d 1154, 1164, 196 USPQ 209, 217 (CCPA 1977). See also
In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

In this case, the examiner has not supplied any evidence that would have made it obvious at the time the invention was made to a person having ordinary skill in the art to have caused Phelps' substrate (i.e., the helical coil) to emit heat so the fibers (i.e., the fibrous woven or braided tubular element or covering) at the interface are secured to the substrate. The examiner's resort to speculation as to how

Phelps' strands are fused to the coil cannot take the place of the necessary evidence. Accordingly, the decision of the examiner to reject claim 1, and claims 2 through 6 dependent thereon, under 35 U.S.C. § 103 is reversed.

Claim 7

We sustain the rejection of claim 7 under 35 U.S.C. § 103.

Claim 7 is drawn to an occlusive device for occluding a lumen or cavity in a mammal, comprising, inter alia, a substrate and a plurality of fibers secured to the substrate and extending from the substrate at an interface therebetween. This claim also states that the fibers are secured to the substrate by causing the substrate to emit heat.

The examiner's position (answer, p. 3) with respect to claim 7 is that

the patentability of the product does not depend on its method of production. The claimed product appears to be the same or very similar to the Phelps et al. product since the end product, in each case, is a substrate coil with fibers melted and fused onto the coil.

The appellants rely on the method limitation of causing the substrate to emit heat as patentably distinguishing over the teachings of Phelps. We do not agree for the reasons that follow.

The appellants have not pointed out any structural difference that would differentiate the occlusive device of claim 7 from the occlusive device taught by Phelps. In addition, the product-by-process limitation set forth in claim 7 (i.e., "secured to said substrate by causing said substrate to emit heat") does not affect the product itself (i.e., the claimed occlusive device) and therefore cannot impart patentability to the product. See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process.).

See also Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 8443-47, 23 USPQ2d 1481, 1488-91 (Fed. Cir. 1992). Once the appellants have been provided with a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the appellants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See In re Marosi, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983). The appellants have not come forward with any evidence to satisfy that burden. Compare In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566-67 (CCPA 1971).

In addition, the appellants assert that there is additional evidence supporting patentability in that in the specification they identified a problem and solved this problem by their invention. We find this argument unpersuasive since the problem identified by the appellants (e.g., detachment of fibers from the coil) was solved by

Phelps. In that regard, Phelps teaches a device for occluding body lumens or cavities having fibers secured to a substrate with free fiber ends extending outwardly from the occlusion device at radially spaced locations on the substrate (see especially Figures 6 and 11 of Phelps). Moreover, it is our view that this evidence is not commensurate in scope with the claimed invention.

For the reasons set forth above, the decision of the examiner to reject claim 7 under 35 U.S.C. § 103 is affirmed.²

Claim 16

Claim 16 is drawn to a device for occluding a body lumen or cavity in mammals, comprising, inter alia, a helically wound coil having a multiplicity of windings defining a lumen and a plurality of fibers having first and second end portions

We note that a disclosure that anticipates under 35 U.S.C. § 102 also renders the claim unpatentable under 35 U.S.C. § 103, for "anticipation is the epitome of obviousness." <u>Jones v. Hardy</u>, 727 F.2d 1524, 1529, 220 USPQ 1021, 1025 (Fed. Cir. 1984). <u>See also In re Fracalossi</u>, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982); <u>In re Pearson</u>, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974).

extending from the coil and a middle portion secured to the coil. This claim also states that the middle portion of the fibers are secured to the coil by emitting heat from the coil.

The appellants rely on the product-by-process limitation that the middle portion of the fibers are secured to the coil by emitting heat from the coil as patentably distinguishing over the combined teachings of Dormandy and Phelps. We do not agree for the reasons set forth above in our discussion of claim 7. Accordingly, the decision of the examiner to reject claim 16 under 35 U.S.C. § 103 is affirmed

Claims 8 to 15 and 17 to 20

The decision of the examiner to reject claims 8 to 15 and 17 to 20 under 35 U.S.C. § 103 is also affirmed since the appellants have not challenged the rejection of these claims with any reasonable specificity, thereby allowing claims 8 to 15 and 17 to 20 to fall with claims 7 and 16 (see <u>In re Nielson</u>, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987).³

CONCLUSION

To summarize, the decision of the examiner to reject claims 1 through 6 under 35 U.S.C. § 103 is reversed and the decision of the examiner to reject claims 7 through 20 under 35 U.S.C. § 103 is affirmed.

 $^{^3}$ 37 CFR § 1.192(c)(7) states that "[m]erely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable."

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR $\S 1.136(a)$.

AFFIRMED-IN-PART

JOHN P. McQUADE Administrative Patent	Judge)))
)
) BOARD OF PATENT
JEFFREY V. NASE) APPEALS
Administrative Patent	Judge) AND
) INTERFERENCES
))
)
)
MURRIEL E. CRAWFORD)
Administrative Patent	Judge)

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APPEAL NO. 1999-2029 - JUDGE NASE APPLICATION NO. 08/431,360

APJ NASE

APJ McQUADE

APJ CRAWFORD

DECISION: AFFIRMED-IN-PART

Prepared By: Gloria Henderson

DRAFT TYPED: 09 Nov 99

FINAL TYPED:

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